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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,054	07/23/2001	Mayumi Tomikawa	522.1921D	4839

21171 7590 06/03/2004

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/910,054

Applicant(s)

TOMIKAWA ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-11, 21 and 24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 5-11, 21 and 24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/23/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/23/01; 2/9/04</u> . | 6) <input type="checkbox"/> Other: ____. |

All objections and rejections not reiterated below are hereby withdrawn. Claims 1-5, 21, and 24 are pending.

Information Disclosure Statement

The information disclosure statement filed 2/20/04, and application 08/014,867 have been considered in full.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5-11 and 24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The amended claims are directed to a computer-implemented process. Amended claim 1 recites a step of displaying data, but does not limit this step to be one which is performed outside the computer; i.e. a physical step or action. A step of merely displaying the results of a computer-implemented process, wherein neither the process itself nor the result is statutory, does not render the process statutory. No physical acts or other "safe harbors" are recited in the claims; however, as set forth in the previous office action, a computer-implemented method comprising only steps of data manipulation MAY be statutory when the result produced is concrete, tangible and useful. The method of claims 5-11 and 24 does not produce a concrete, tangible and useful result, as previously set forth and further elucidated below.

As set forth in MPEP 2106.IV.B:

“In practical terms, claims define nonstatutory processes if they:

- consist solely of mathematical operations without some claimed practical application (i.e., executing a “mathematical algorithm”); or
- simply manipulate abstract ideas, e.g., a bid (Schrader, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application.”

And at MPEP 2106.IV.B.2(b) (ii):

“A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See AT &T, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in State Street, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being claimed (as in Alappat, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc). For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory.

The “practical application” toward which the claims are apparently directed is the analysis of a three dimensional structure. The claims recite steps of calculation and display of 3D structures corresponding to two sets of points. There is no recited step of determining or indicating a degree of similarity between the structures, or of calculating

similarity to known structures. The result of the mathematical calculation, per se, is not a concrete, tangible, and useful result as one skilled in the art would not know what the result is intended to indicate.

Applicant's arguments filed 2/9/04 have been fully considered but they are not persuasive. In response to the argument that a step of displaying results renders the claims statutory, it is noted, as set forth above, that merely displaying the result of a calculation does not render claims statutory. What is "concrete, tangible, and useful" about a "picture" (i.e. graphic display in 3D) of two point sets with an unknown degree of similarity? For example, one may display a picture and its copy in a museum. This is appreciated by the public, but does not render the picture, its copy, nor the act of either displaying or viewing both (i.e. side by side), statutory subject matter under 35 USC 101. For these reasons, and those previously set forth, the examiner maintains that the claims do not recite statutory subject matter, and maintains the rejection.

Claims 5-11, 21, and 24 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Applicant has not set forth any arguments specific to this rejection.

The claims recite a method and apparatus for performing the method, for analyzing three dimensional structures. The claimed method steps result in calculation of a root mean square distance between elements belonging to two point sets. These point sets are not limited to be from two different structures, therefore the claims encompass comparison of point sets from different areas of domains of the same

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compound or molecule. The specification does not disclose a utility for comparing different parts of the same compound or molecule and none is apparent. The claim also encompass point sets from two different structures, whereupon the method may presumably be used to compare different compounds or molecules. A “use” of the inventive method for comparing different compounds (e.g. enzymes) is set forth and exemplified in the specification on pages 46-52. However, while the example of the specification provides results of the comparison, there is no disclosure for what one skilled in the art would, in fact, use this information *for*. The specification also asserts, on page 5, that the inventive method may be used to extract motifs. However, an extraction of motifs requires a determination of a degree of similarity between two proteins/sequences/structures. The claims do not recite any step or limitation for determining a degree of similarity. Merely elucidating how far apart elements of compounds are is not an indication that the compounds are, in fact, similar enough to identify the elements as comprising (presumably conserved) motifs, or are different, such that the elements can be eliminated from further consideration/comparison. The claims do not identify any particular compounds for comparison. With no knowledge of identity, function, etc. of the structures being compared, nor any determination of a degree of similarity between two structures, the claims do not provide an “immediately useful” result. According to MPEP 2107.01 and as set forth in *Brenner v. Manson* (148 USPQ 689 (1966)) and *In re Ziegler* (26 USPQ2d 1600), a “useful invention” is one wherein the “usefulness” is “immediately apparent to those familiar with the technological field of the invention. As further set forth in MPEP 2107.01, a “use” to do

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further research, or assaying for or identifying a compound which itself has no, or an unknown utility, is not considered a "substantial utility" under 35 USC 101. As the structures being "assayed" are unknown/not identified in the claim, their utility is unknown. More information and/or further research would be required by one skilled in the art to know what to do/how to use the results of the claimed method and apparatus, as set forth above. For these reasons, the examiner maintains that the claims lack utility, and maintains the rejection.

Claims 5-11, 21, and 24 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-11, 21, and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

A method or apparatus comprising a step or means for generating a combination of correspondence satisfying a condition, as recited in claims 5 and 21, is not enabled as neither the specification nor prior art provide guidance for how to determine if a combination of correspondence “satisfies” a condition. The instant specification discloses/exemplifies on pages 27 et seq. various methods of analyzing three dimensional structures. The specification admits on page 29 that merely comparing two data sets (i.e. merely generating a “combination of correspondence” between two data sets) renders it “nearly impossible” to effect a calculation (of rmsd?) since so many combinations are possible. The disclosure of the specification, therefore, indicates that some sort of “condition” must be met in order to enable the inventive method. Page 30 then discloses that an “optimum combination” must be generated “in view of” a geometric relationship within the data sets, a threshold value condition, and an attribute of points. Following pages exemplify “ordering” points, refining candidates based on a distance relationship, on angle relationships, or on distances and angles from a center of gravity, and using a threshold value condition. Nowhere does the specification teach how to determine if these “conditions” are met or “satisfied” by a combination of correspondence (i.e. comparison of data). Rather, it appears that the “conditions” of the specification are used to compare data sets, or *create* combinations of correspondence.

There is no disclosure for how to determine what requirements must be met in order to determine if a particular combination (comparison) "satisfies" the condition.

Figures 15 and 17 comprise flow charts which appear to correspond, at least in part, with the claimed method and apparatus. These Figures contain an box asking if a previous step "satisfies a restriction condition?" but neither Figure sets forth any step or means for determining what conditions are required in order to determine a "yes" or "no" answer. Figures 36 and 37 comprise flow charts which appear to reflect generating a correspondence of data based on conditions similar to those disclosed in the specification, and disclose particular equations for selecting data from a single data set BEFORE determining a correspondence with a second data set. The claims specifically recite generating a combination of correspondence satisfying a condition BETWEEN elements of a first set and elements of a second set (of data), therefore Figures 36 and 37 do not appear to be a teaching for how to perform the claimed method or how to use the claimed apparatus.

The prior art of PANTOLIONO (IDS ref: US patent 4,853,871) teaches a method for analyzing and comparing three dimensional structures using 3D coordinates and calculation of root mean squares to determine fit; i.e. distance (col. 8, lines 32-65), but does not teach that any "conditions" must be met or satisfied in order to generate the comparison and/or perform the root mean square calculation.

The level of skill in the art is considered to be high. However, given the lack of guidance in either the specification or the prior art for how to determine whether a combination of correspondence between two point sets meets or satisfies a condition,

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and as one skilled in the art would be required to guess at the parameters necessary to perform such a determination or calculation, it would require undue experimentation by one skilled in the art to generate a combination of correspondence satisfying a condition. For these reasons, the claims are not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 21 recite generating a combination of correspondence “satisfying” a condition. As set forth above, the specification does not disclose what requirements must be met in order for a combination of correspondence to “satisfy” a condition. The claims do not recite any such requirements. As the metes and bounds intended by applicant with regard to “satisfaction” of a condition are not defined by the specification or in the claims, applicant’s intended limitations are unclear and the claims are indefinite.

Response to Arguments

In response to applicant’s apparent argument that deletion of the term “restriction” overcomes both the enablement and indefiniteness rejections, it is noted that one skilled in the art would still not know how to determine if a “condition” is met, as set forth above, nor what is required to “satisfy” the condition, therefore the examiner maintains that the claims are indefinite and are not enabled.

Conclusion

Claims 5-11, 21 and 24 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
6/1/04

mam